

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR CONFIRMATION NO. 10/633,343 08/01/2003 Peter A. Burke ST8635US 3733 **EXAMINER** 22203 02/24/2006 7590 **KUSNER & JAFFE** MCKANE, ELIZABETH L **HIGHLAND PLACE SUITE 310 ART UNIT** PAPER NUMBER 6151 WILSON MILLS ROAD HIGHLAND HEIGHTS, OH 44143 1744

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary Loigh McKane	.S. Patent and Trademark Office PTOL-326 (Rev. 1-04)	Office Action	n Summary	Part of Paper No./Mai	Date 022106	
## Disposition of Claims 10/633,343 BURKE ET AL. Examiner Art Unit Leigh McKane 1744 - The MAILING DATE of this communication appears on the cover sheet with the correspondence address → Period for Reply	Notice of Draftsperson's Patent Drawing Road Information Disclosure Statement(s) (PTO-Paper No(s)/Mail Date		Paper 5) Notice	No(s)/Mail Date of Informal Patent Application (PTG	O-152)	
Office Action Summary Leigh McKane				•		
Office Action Summary Examiner	Oce the attached detailed Offic	c action for a fist Of (me cermien cohies	not received.		
Office Action Summary Leigh McKane		•		not received		
## Diffice Action Summary Examiner	3. Copies of the certified of	copies of the priority	documents have be		Stage	
## Diffice Action Summary Examiner		•		in Application No		
## Diffice Action Summary Examiner			ave been received.			
Office Action Summary Examiner			only under 35 U.S.	C. 9 119(a)-(a) or (t).		
Office Action Summary Examiner		claim for foreign pri	iority under 25 11 C	C & 110(a) (d) or (f)		
Office Action Summary Examiner	Priority under 35 U.S.C. § 119					
Disposition of Claims 10/633,343 BURKE ET AL.	11) The oath or declaration is object	ected to by the Exam	niner. Note the attac	ched Office Action or form P	ГО-152.	
Office Action Summary Light McKane Light McKan					FR 1.121(d).	
## Display to the Communication of the mailing date of this communication appears on the cover sheet with the correspondence address — Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (b) MONTHS from the mailing date of this communication. If the period for reply septied above, the majorimum statutory period will apply and will expire SIX (b) MONTHS from the mailing date of this communication. If the period for reply septied above is best thin thiy (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If the period for reply septied above is best than this (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If the period for reply septied above, the majorimum statutory period will apply and will expire SIX (b) MONTHS from the mailing date of this communication of the statutory period will apply and will expire SIX (b) MONTHS from the mailing date of this communication of the statutory period will apply and will expire SIX (b) MONTHS from the mailing date of this communication of the communication of the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 23 November 2005. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1,3.9.12.16 and 21-26 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) 1,3.9.12.16,19 and 22 is/are rejected. 7) Claim(s) 1,3.9.12.16.19 is/are allowed. 6)		•	,	•		
Office Action Summary 10/633,343 BURKE ET AL.	•	•	ed or b)☐ objected	to by the Examiner.		
## Diffice Action Summary The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply	9) The specification is objected to	o by the Examiner.				
## Diffice Action Summary The MAILING DATE of this communication appears on the cover sheet with the correspondence address	Application Papers					
## Diffice Action Summary The MAILING DATE of this communication appears on the cover sheet with the correspondence address	8) Claim(s) are subject to	restriction and/or el	lection requirement			
## Disposition of Claims 10/633,343 BURKE ET AL.	<u> </u>	•				
Office Action Summary Examiner						
Office Action Summary Examiner	·					
Office Action Summary Examiner	4a) Of the above claim(s)	is/are withdrawn	from consideration.	•		
Office Action Summary Examiner	4) Claim(s) 1,3-9,12-19 and 21-	26 is/are pending in	the application.			
Office Action Summary Examiner Leigh McKane 1744 The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is test than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 23 November 2005. 2a) This action is FINAL. 2b) Nice this application is in condition for allowance except for formal matters, prosecution as to the merits is	Disposition of Claims					
Office Action Summary Examiner Leigh McKane 1744 The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is test than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 23 November 2005. 2a) This action is FINAL. 2b) Nice this application is in condition for allowance except for formal matters, prosecution as to the merits is	ciosed in accordance with the	: practice under Ex p	barte Quayle, 1935	U.D. 11, 453 U.G. 213.		
Office Action Summary Examiner Leigh McKane 1744 - The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply secified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communicatio Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 23 November 2005. 2a) This action is FINAL. 2b) This action is non-final.					e merits is	
Office Action Summary Examiner	<u> </u>	• —				
Office Action Summary Examiner Leigh McKane 1744 The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status						
Office Action Summary Examiner Leigh McKane 1744 The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).	<u></u>					
Office Action Summary 10/633,343 BURKE ET AL.	 after SIX (6) MONTHS from the mailing date of If the period for reply specified above is less tha If NO period for reply is specified above, the ma Failure to reply within the set or extended period Any reply received by the Office later than three earned patent term adjustment. See 37 CFR 1. 	this communication. In thirty (30) days, a reply with thirty (30) days, a reply will a simum statutory period will a differ reply will, by statute, can emonths after the mailing day.	thin the statutory minimum on the statutory minimum on the statutory minimum on the statutory minimum of the statutory mi	of thirty (30) days will be considered time MONTHS from the mailing date of this one ABANDONED (35 U.S.C. § 133).		
Office Action Summary Examiner Leigh McKane 10/633,343 BURKE ET AL. Art Unit 1744 The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply	THE MAILING DATE OF THIS COM	MMUNICATION.		_ , ,		
Office Action Summary Examiner Leigh McKane 10/633,343 BURKE ET AL. Art Unit 1744 - The MAILING DATE of this communication appears on the cover sheet with the correspondence address	• •	SIUU EUB BEBI A 16	S SET TO EVOIDE	3 MONTH(S) EDOM		
Office Action Summary 10/633,343 Examiner BURKE ET AL. Art Unit		ommunication appea	rs on the cover shee	et with the correspondence a	ddress	
Office Action Summany 10/633,343 BURKE ET AL.		L	eigh McKane	1744		
	Office Action Summa	ary E	xaminer	Art Unit		
			10/633,343	BURKE ET AL.		
Application No. Applicant(s)		. 4	Application No.	Applicant(s)		

Application/Control Number: 10/633,343 Page 2

Art Unit: 1744

Specification

1. The amendment filed 23 November 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment to lines 20-21 of claim 1, wherein it is recited that the "bypass line is connected at one end to said fluid feed line between said directional valve and said water inlet line", introduces new matter into the disclosure. As described by the specification and illustrated in Figure 2, the bypass line 172 is connected at one end to the fluid feed line 62 between the directional valve 174 and the recirculation line 88, not the water inlet line 42.

Claim Rejections - 35 USC § 112

- 2. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As set forth above, in lines 20-21 of the claim, the amendment has introduced subject matter which was not described in the specification. The amendment recites that the "bypass line is connected at one end to said fluid feed line between said directional valve and said water inlet

Application/Control Number: 10/633,343

Art Unit: 1744

line". However, as described by the specification and illustrated in Figure 2, the bypass line 172 is connected at one end to the fluid feed line 62 between the directional valve 174 and the recirculation line 88.

Applicant is required to cancel the new matter in the reply to this Office Action.

- 4. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 5. Claims 1, 3, 9, 12, 16, 19, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 15, "said supply line" lacks positive antecedent basis, as no "supply line" has been previously recited. The examiner suggests changing "supply line" to –water line--.

In claim 3, "first and second elements" lacks positive antecedent basis as previously these "elements" were named "first and second *filter* elements."

In claim 9, line 7, "said sterilizer" renders the claim vague and indefinite since an apparatus cannot be used to define itself. The examiner suggests changing "said sterilizer" to –said sterilizing chamber--. In line 19, "a first intersection" renders the claim vague and indefinite, as it implies the existence of a "second" or subsequent intersection, where there is none.

In claim 12, "said source of pressurized water" lacks positive antecedent basis as no such source has been previously recited.

In claim 16, a means for "pressuring"/"pressurizing" the upstream side of each filter is claimed twice. Is this the same element or two different elements?

Similarly, in line 12 of claim 19, a recitation of "a first intersection" renders the claim vague and indefinite, as it implies the existence of a "second" or subsequent intersection, where there is none.

In claim 22, "each sterile processing phase" renders the claim vague and indefinite as what constitutes a "sterile processing phase" has not been defined by the claims.

Allowable Subject Matter

- 6. Claims 1, 3-9, 12-19, 21, and 22 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.
- 7. The following is a statement of reasons for the indication of allowable subject matter: With respect to claims 1, 9, and 19, the prior art of record, while teaching a bypass line in a reprocessing apparatus, fails to teach or suggest the structure as set forth in the amended claims.
- 8. Claims 23-26 are allowed.
- 9. The following is an examiner's statement of reasons for allowance: The closes prior art with respect to the method of checking the filter integrity, Nakanishi et al. JP, teaches the use of pressure measurements to test a single filter in an endoscope reprocessor. However, Nakanishi et al., fails to teach or suggest the specific method of filter integrity testing as set forth in claim 23.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

Art Unit: 1744

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for

Allowance."

Conclusion

10. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The

examiner can normally be reached on Monday-Thursday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leigh McKane

Primary Examiner

Art Unit 1744

elm

21 February 2006